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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,090	09/11/2003	Jay S. Schneider	08321-0113 US1	5901

23973 7590 11/17/2005

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/660,090

Applicant(s)

SCHNEIDER, JAY S.

Examiner

Phyllis G. Spivack

Art Unit

1614

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 16-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10-31-03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1614

Applicant's Response filed September 16, 2005 to the Restriction Requirement is acknowledged. Applicant has elected Group I, claims 1-15, drawn to treating Parkinson's disease comprising administering levodopa and a partial glycine agonist and, optionally, a peripheral decarboxylase inhibitor.

Accordingly, claims 16-42 are presently withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. Re-affirmation of the election is requested when Applicant responds to this Office Action.

An Information Disclosure Statement filed October 31, 2003 is further acknowledged and has been reviewed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3 and 4 of U.S. Patent No. 6,551,993.

Art Unit: 1614

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed to treating Parkinson's disease comprising administering levodopa/carbidopa and a partial glycine agonist selected from the group consisting of D-cycloserine, D-serine and serine racemase. The "high dose" required by instant claim 1 is met by the dosing disclosure in the patent in columns 6-7.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The recitation in claim 1 "high dose" is vague and indefinite. Applicant should recite the "high" dosage range contemplated, as disclosed on page 6 of the specification.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as lacking a clear written description of the invention and of the manner and process of practicing it, and in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the same, and, as not setting forth the best mode contemplated by the inventor to carry out the invention with respect to the administration of the partial glycine agonists D-serine, ACPC and serine racemase.

Claim 1 is directed to a therapeutic treatment of Parkinson's disease comprising administering the combination of levodopa and a high dose of any partial glycine agonist. The specification provides Examples 1-4 on pages 13-14 wherein D-

Art Unit: 1614

cycloserine is administered with levodopa. There is no guidance provided for the administration of any other partial glycine agonist such as D-serine, ACPC and serine racemase. Accordingly, there is no showing that Applicant had possession of the claimed invention of therapeutic treatments involving any other partial glycine agonist other than D-cycloserine. The present level of skill in the neurology art in effective treatment modalities for Parkinson's disease is immature. Thus, it would have been reasonable to require a more detailed written description directed to treatment involving the administration of the partial glycine agonists D-serine, ACPC and serine racemase.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro, H.K., U.S. Patent 5,668,117, in view of Schneider, J.S., U.S. Patent 5,668,117.

Shapiro teaches a pharmaceutical composition for use in the treatment of Parkinson's disease optionally comprising levodopa or levodopa combined with the peripheral dopa decarboxylase inhibitor carbidopa and the partial glycine agonist D-cycloserine. See column 66, claim 2 (medicaments a and j). Shapiro fails to characterize the dose of the partial glycine agonist as "high". However, Schneider teaches a dosage described as "large" in column 7, lines 2-3. This 8mg/kg dose meets the requirement of instant claim 8, which is considered "a high dose". The determination of optimal dosage regimens and optimal modes of administration are

Art Unit: 1614

parameters well within the purview of those skilled in the neurology art through no more than routine experimentation.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 4, 2005


Phyllis G. Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**